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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/530,046

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Yukiko Yokoi

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WENDEROTH, LIND & PONACK, L.L.P.

1030 15th Street, N.W.,

Suite 400 East

Washington, DC 20005-1503

EXAMINER

JEAN-LOUIS, SAMIRA JM

ART UNIT

PAPER NUMBER

1627

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/530,046	<b>Applicant(s)</b> YOKOI ET AL.	
	<b>Examiner</b> SAMIRA JEAN-LOUIS	<b>Art Unit</b> 1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19, 32-34 and 39-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19, 32-34, and 39-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/06/09</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

This Office Action is in response to the amendment submitted on 11/06/09. Claims 1-19, 32-34, and 39-41 are currently pending in the application, with claims 20-31 and 35-38 having being cancelled. Accordingly, claims 1-19, 32-34, and 39-41 are being examined on the merits herein.

Receipt of the aforementioned amended claims, Information Disclosure Statement (IDS), and Translated Foreign Priority Document is acknowledged and have been entered.

Applicant's argument with respect to the rejection of claims 1-19 and claims 20-26, and 31-40 over Ohta in view of Nakamura and in further view of Hoffman has been fully considered. Applicant further argues that Ohta's correct priority date is November 07, 2002 instead of July 11, 2002. Applicant additionally presented a translated version of the Japanese Priority Document JP 2002-290367. As a result, the Examiner contends that the earliest priority date of the instant invention is October 02, 2002. Ohta (WO 02/ 087588), published on November 07, 2002, is no longer available as prior art. Consequently, the rejection of claims 1-19 over Ohta in view of Nakamura and rejection of claims 20-26 and 31-40 in further view of Hoffman are hereby withdrawn.

For the foregoing reasons, the rejections of record are hereby withdrawn. The following modified 103 (a) Non-Final rejection is being made.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1-19, 32-34, and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Onodera et al. (U.S. Patent 6,486,149 B2, previously cited) in view of Nakamura (Foods and Food Ingredient Journal of Japan, 1999, Vol. 180, pg. 1, previously cited).**

Onodera et al. teach a process of making amorphous cefditoren pivoxil with a water soluble high molecular additive (instant claims 33-34; see abstract). Onodera et al. additionally disclose that orthorhombic crystalline Cefditoren pivoxil had several advantages of high purity, high thermal stability and high storage stability, but that it was unsuitable for use in an oral dosage form due to its poor water solubility (see col. 2, lines 44-50). To overcome this poor water solubility, Onodera et al. teach that, "it is known that an amorphous substance generally has a high solubility in water, as compared with that of the corresponding crystalline substance" (see col. 2, lines 63-66

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and col. 3, lines 6-8). Onodera et al. further teach that an orally administrable amorphous and water soluble substance of Cefditoren pivoxil is obtained when Cefditoren pivaloyloxymethyl ester is homogenously mixed with a water-soluble high-molecular additive such as a water-solubilized derivative of cellulose and which include hydroxypropylmethyl cellulose (instant claims 3-4, 6-8, and 12-19) and a pharmaceutically acceptable alkali metal salt or alkaline earth metal salt of an alginic acid ester of propylene glycol (see col. 3, lines 46-59; col. 6, lines 48-67 to col. 7, lines 1-43; col. 15 Example 2, wherein hydroxypropylmethyl cellulose is used; and Example 7 spanning col. 20-21 ). Importantly, Onodera et al. teach that the water-soluble high molecular additive co-existent in admixture with Cefditoren pivoxil in the solid particles can possess a function capable of inhibiting the molecule of Cefditoren pivoxil from undergoing into crystallization (see col. 5, lines 42-46).

Onodera et al. do not teach addition of a sucrose fatty acid ester into the aforementioned composition. Similarly, Onodera et al. do not teach a weight ratio of the sucrose fatty acid ester to the cefditoren pivoxil in a range of 0.008 to 0.816 or that the polymer is in a weight ratio range of 0.008 to 0.816.

Nakamura teaches that sucrose fatty acid ester (SE) has eight hydroxyl groups in the hydrophilic group and so it is possible to manufacture SE ranging from low HLB to high HLB by controlling the degree of esterification (see pg. 1). Nakamura additionally

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teaches that SE possesses solubilizing properties and can inhibit crystal growth (see pg. 1).

While the exact ratio of the sucrose fatty acid ester and polymer is not disclosed by Onodera, the Examiner contends that it is well within the purview of the skill of the artisan at the time of the invention to adjust the concentration and range of the sucrose fatty acid ester and/or the polymer of the composition during the course of routine experimentation so as to obtain the desirable type of properties (i.e. inhibition of crystals) in the composition. Additionally, because Onodera et al. do not teach addition of polysorbate-80 to the composition, the Examiner contends that the composition is indeed devoid of polysorbate-80 (instant claim 32).

Thus, to one of ordinary skill in the art would have found it obvious to add sucrose fatty acid ester to the composition of Onodera since Nakamura teaches that sucrose fatty acid ester (SE) is able to inhibit the formation of crystals in compositions. Moreover, it would have been obvious to one of ordinary skill in the art at the time of the invention to vary the ratio of the sucrose fatty acid ester for the purpose of inhibiting crystals or for solubility purposes. Consequently, one of ordinary skill in the art would have been motivated to add SE and vary its concentration in view of the disclosure of Nakamura with the reasonable expectation of providing a composition that possesses high stability and high dissolvability.

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While Onodera does not explicitly teach the retention time of the amorphous characteristics of the aforementioned composition, the Examiner maintains that given that the goal of the invention was to obtain an amorphous cefditoren pivoxil composition, such composition does indeed retain its amorphous character in aqueous medium for at least one day. Furthermore, given that these characteristics are obtained as a result of mixing the pharmaceutically active ingredient with a sugar fatty acid ester, the Examiner concludes that the modified composition of Onodera necessarily maintains its amorphous character. If however applicant disagrees, it is incumbent upon applicant to demonstrate through comparative results that the composition of Onodera does not maintain its amorphous character.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1627

01/20/2010

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627